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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,888	10/19/2004	Dirk Cremer	5942/83518	4210

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1613	
MAIL DATE	DELIVERY MODE
01/13/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,888	CREMER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-12,15,16 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 7-12, 15, 16 abd 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges receipt of amendment after final rejection, notice of appeal and remarks filed 12/22/2010.

2. Kiliaan (WO 0184961) in view of della Valle et al. (US 4,595,680) is withdrawn because the combined reference does not teach "5 to 20 weight percent" and prosecution is opened.

3. Claim 6 has been canceled.

4. Claims 1-3, 5, 7-12, 15, 16 and 18-24 are pending.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

6. The recitation of "paste like at room temperature" in original claim 1 and now in previously presented claims 20 and 22 (presented 11/26/08) does not derive antecedent support basis from the specification.

7.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-3, 5, 7-12, 15, 16 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 20-22 recite phosphatidyl serine as being present at amounts of 15-40% and this range was not envisioned at the time the application was filed.

11. What was envisioned is 10-40% and 15-30% by weight (see paragraph [0023] of the published application) and the broader range of 5-98%. The original specification is clear in that after the initial 5-98% (abstract, paragraph [0018] and original claim 1), paragraph [0023] disclosed the other ranges for the phosphatidyl serine at 10-40% and 15-30% by weight.

12. Applicant I the amendment after final points to claims 2 and 6 as providing the support. Support for 15-40 is not in claim 2 and the examiner does not find the support and applicant does not also provide the reasons for the support or where the support can be found.

13. The rejection would be overcome by removing the 15-40% from the claims.

14. Claims 1-3, 5, 7-12, 15, 16 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claims 1 and 20 are directed to a solid matrix encapsulated with a cater containing coating, the matrix comprises a bioactive component, 15-40% by weight phosphatidyl serine, 1-90% by weight phosphatidyl choline and 1-94% by weight of at least one further matrix

component, the further matrix component includes a fat component, a wax component, and optionally a polyol component and physiologically compatible additive, …, 5-20 wt% wax component, and optionally 2-20 wt% polyalcohol component, 1-5 wt% physiologically compatible additive, …coating.

16. It is unclear where the 5-20 wt% wax, 2-20 wt% polyol component and the 1-5 wt% physiologically compatible additive fits or their relationship to the 1-94% by weight of at least one further matrix component?

17. The same issues are also present in claims 21 and 22.

18. It is respectfully suggested that the claims be amended to remove the seeming ambiguity in the claims.

19. Claims 20 and 20 are solid matrix composition. But the claim also states that the bioactive component and the further matrix component are present in amounts to make the bioactive containing matrix solid or paste-like at room temperature. While "in amounts and ratios" are any amounts that would be effective to make solid or paste-like is the property characteristic of the composition, it is unclear how a solid turns to paste-like.

20. In claim 5, the fat component is selected from the group consisting of "refined, hydrogenated, fractionated fat, and combinations thereof." Refined, hydrogenated, fractionated fat do not appear to be members of a group. It appears that the fat is selected from refined fat, hydrogenated fat, fractionated fat and combinations thereof and the claim 5 is examined as that. It is respectfully suggested that the claim be amended to recite the fat component in such a way that they are part of a group, that is, ---a fat component selected from the group consisting of refined fat, hydrogenated fat, fractionated fat and combinations thereof---.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 1-3, 7-12, 15, 16, 18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of Winston, Jr. et al. (US 5,342,626).

24. Kiliaan discloses a capsule containing phospholipid comprised of phosphatidyl serine and phosphatidyl choline; the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; the composition meeting the limitations of claims 1-3, 5, 15, 16 and 20-23 in the sense that phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids meeting the percent limitation in claim 2; the DHA and EPA omega fatty acids meet the fractionated fat of claim 5. The composition of Kiliaan is administered to treat vascular disorders/dementia syndromes (page

1, lines 6-9) meeting claim 15. On page 6, lines 21-30, Kiliaan discloses that the composition of contains eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), arachidonic acid at a ratio of EPA +DHA to DHGLA +AA of 2.5 to 5.5%, or mixtures. EPA and DHA are fat and phospholipids are also fats. In Example 1, the amount of the fat is at (50 + 75 + 250)/830.3 = ~45% anticipating the limitation of 20-50% fat in claims 1 and 20-22. The phosphatidyl serine at 14.4% anticipates the requirement that the phosphatidyl serine be at a range of 15-40% in claims 1 and 20-22, 15-30% in claims 2, 16 and 23. The phosphatidyl choline at 15.6% anticipates the requirement that the phosphatidyl choline be at a range of 1-90% in claims 1 and 20-22; and 2.0-20% in claims 3 and 23. The presence of fat (the omega fatty acids and the phospholipids) and vitamins (Example 1 and claims 10 and 11) meet the requirement for the presence of broad fat and additives in claims 1 and 20-22. The capsule meets the limitation that the solid matrix is encapsulated and since capsule is a solid, the capsule meets the solid limitation of the claims and also the powdered formulations and the bar formulation that is coated with chocolate meets the limitation of solid formulation.

25. Kiliaan discloses the claimed composition by teaching solid compositions comprising phosphatidyl choline, phosphatidyl serine and fat in the amount recited. Kiliaan uses the composition to treat vascular disorders including dementia.

26. While the composition of Kiliaan is encapsulated, Kiliaan is silent regarding presence of water or moisture containing coat(ing).

27. But, Winston, Jr. discloses that gelatin polymers and non-gelatin materials can be used in encapsulation, that these polymers such as gellan gum, carrageenan and mannan gum re-melt under controlled conditions to form soft capsules that seal encapsulated contents (see the entire

document with emphasis on the abstract, column 1, lines 7-12 and 62-68; column 2, lines 9-18). The %water in capsule after solvent removal and drying is at a predetermined amount of 3-4% (column 4, lines 59-65; column 7, lines 51-55). The gelatin free capsule shell of Winston, Jr. further comprises plasticizers selected form sorbitol, glycerin, propylene glycol, corn syrup, sucrose, fructose and polyethylene glycol and mixtures (column 4, lines 42-47; claim 3). The carrageenans and sorbitol meet claims 8 and 9. The capsule of Winston, Jr. may also contain dyes (column 8, lines 12, 13) so that claim 10 is met. Winston, Jr. teaches that the water insoluble liquids are microencapsulated, that the encapsulation masks the taste of unpleasant tasting compositions and further protects oxidation of these compositions and allows for controlled release of these compositions (column 8, lines 14-19). Thus, with regards to claim 11, one having ordinary skill in the art would be motivated to use amounts of the coating or encapsulating material relative to the composition that would provide effective masking of the taste, provide the desired controlled release of the composition and be also effective in protecting the composition from oxidation so that the ratio of the coating to the bioactive agent would be obvious. The 3-4% moisture content of the capsule shell anticipates the water/moisture content of 1.0 to 10.0% of claim 7. Since Winstson, Jr. contemplates microencapsulation or microcapsules and because microcapsules would have diameters in the micrometer range, the microcapsule of Winston would be expected to fall within the diameter recited in claim 12. There is no demonstration that the recited diameter of the matrix provides unexpected results.

28. Therefore, taking the teaching of Kiliaan et al. (WO 0184961) Winston, Jr. et al. (US 5,342,626), one having ordinary skill in the art at the time the invention was made would reasonably expect that the presence of moisture in the capsule would effectively control the

melting temperature and proper sealing of the capsules so that the requirement that the matrix is encapsulated with water containing coating in claims 1, 20, 21 and 22 is met.

29. Since claims 1 and 20-22 say at least one further matrix component and the fat and the wax being part of the at least one further matrix component, claims 1 and 20-22 do not have to have a wax and these claims are examined as not having wax.

Response to Arguments

30. Applicant's arguments filed 12/22/2010 as the arguments apply to the current rejections have been fully considered but they are not persuasive.

31. Applicant argues that Kiliaan does not disclose 5-20% of a wax component.

32. Response: The examiner agrees. But claims 1 and 20-22 do not require a wax because, claims 1 and 20-22 say at least one further matrix component and the fat and the wax being part of the at least one further matrix component, claims 1 and 20-22 do not have to have a wax and these claims are examined as not having wax.

33. Applicant argues that Winston Jr. does not disclose or suggest that stable solid matrix containing phosphatidyl serine and phosphatidyl choline can be encapsulated with water containing coating so that applicant is of the view that Winston Jr. does not cure the deficiency of Kiliaan.

34. Response: The examiner disagrees because the claims are not directed to how to stabilize phosphatidyl serine and phosphatidyl choline containing composition by encapsulating with water containing coating. In fact the specification does not identify that aspect as one of the problems solved by the current invention (see paragraphs [0014]-[0019] and [0024] of the published application).

35. No claim is allowed.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613